orspec pharma
part of uniphar

31 January 2024

**Shortage of HEPARIN SODIUM 5000IU/5mL (porcine mucous) injection ampoule and alternative supply arrangement under Section 19A of the Therapeutic Goods Act**

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma to notify your organisation that due to the shortage of **HEPARIN SODIUM 5000IU/5mL (porcine mucous) injection ampoule, (AUST R 49232).** ORSPEC Pharma has arranged the supply of an alternative product on a temporary basis.

**Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion – Preservative Free (Wockhardt)** is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the Therapeutic Goods Act, 1989 until **30 April 2024.**

**Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion – Preservative Free (Wockhardt)** is approved for use under Section 19A for the following indications:

- *Treatment of deep vein thrombosis, pulmonary embolism, unstable angina pectoris and acute and peripheral arterial occlusion*
- *In extracorporeal circulation and haemodialysis*

**Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion – Preservative Free (Wockhardt)** is registered in the United Kingdom and all labelling is in English.

Please note the following differences between, **HEPARIN SODIUM 5000IU/5mL (porcine mucous) injection ampoule, (AUST R 49232)** and **Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion – Preservative Free (Wockhardt)** to be supplied under section 19A:

| | **HEPARIN SODIUM 5000IU/5mL (porcine mucous) injection ampoule, (AUST R 49232)** | **Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion – Preservative Free (Wockhardt) (PL 29831/0105)** |
|---|---|---|
| Excipient ingredients | • Water for injections | • Water for injections<br>• Sodium hydroxide solution<br>• Hydrochloric acid |

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| Administration details | Heparin may be given by intermittent intravenous injection, intravenous infusion or deep subcutaneous injection. | By continuous intravenous infusion or by intermittent intravenous injection. |
| Pack presentation | 10 x ampoules<br>50 x ampoules | 10 x glass ampoules |

For dosing and administration information, Please refer to the Australian Product Information for heparin available at
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-06999-3

**Adverse Event Reporting**

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion – Preservative Free (Wockhardt),** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at customerservice@orspecpharma.com. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

Please forward this information to relevant staff members in your organisation.

For further information, please contact ORSPEC Pharma on 024 339 4239 or email customerservice@orspecpharma.com.

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma